

Unlocking the Power of Harmonized Data: Driving Operational Decision Making and Strategic Insights

Daniel Rolo

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About the Speaker

Daniel graduated from the University of the Free State in 2012 with a B.Sc. degree in Computer Science and is currently a Statistical Programming Director with over 10 years' experience in the CRO industry. His current role encompasses strategic innovation and initiatives to help drive the next generation of statistical programming and data science, with the aim of elevating the capabilities and efficiency of programming teams in delivering world-class quality deliverables and data-driven insights.

Daniel is passionate about technology and process improvement; he is keen on people development and fostering an inclusive culture of promoting excellence by collaborating with teams from around the world.

Daniel believes we have entered a golden age of statistical programming and is eager to see what the next 10 years will be like for the industry.



Agenda

- › The Data Revolution
- › The New “Normal” in Clinical Development
- › Central Harmonized Data Model
- › Implementation of Context-Specific Dashboards
- › Onward to the Future
- › Q&A

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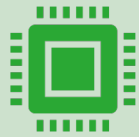
The world's most valuable resource is no longer oil, but data.

”

The Economist

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The Data Revolution



We are living in an era of data abundance. Every second, an astounding amount of data is generated across various platforms, devices, and systems. In the clinical development industry, this includes everything from patient-reported outcomes and wearable device data to genomic information and real-world evidence.



However, much of this data remains untapped, its potential unexplored. The challenge lies not in collecting data, but in effectively integrating, analyzing, and deriving actionable insights from it. This data revolution presents both a challenge and an opportunity for the clinical development industry to redefine its processes and outcomes.

“

The advance of technology is based on making it fit in so that you don't even notice it, so it's part of everyday life.

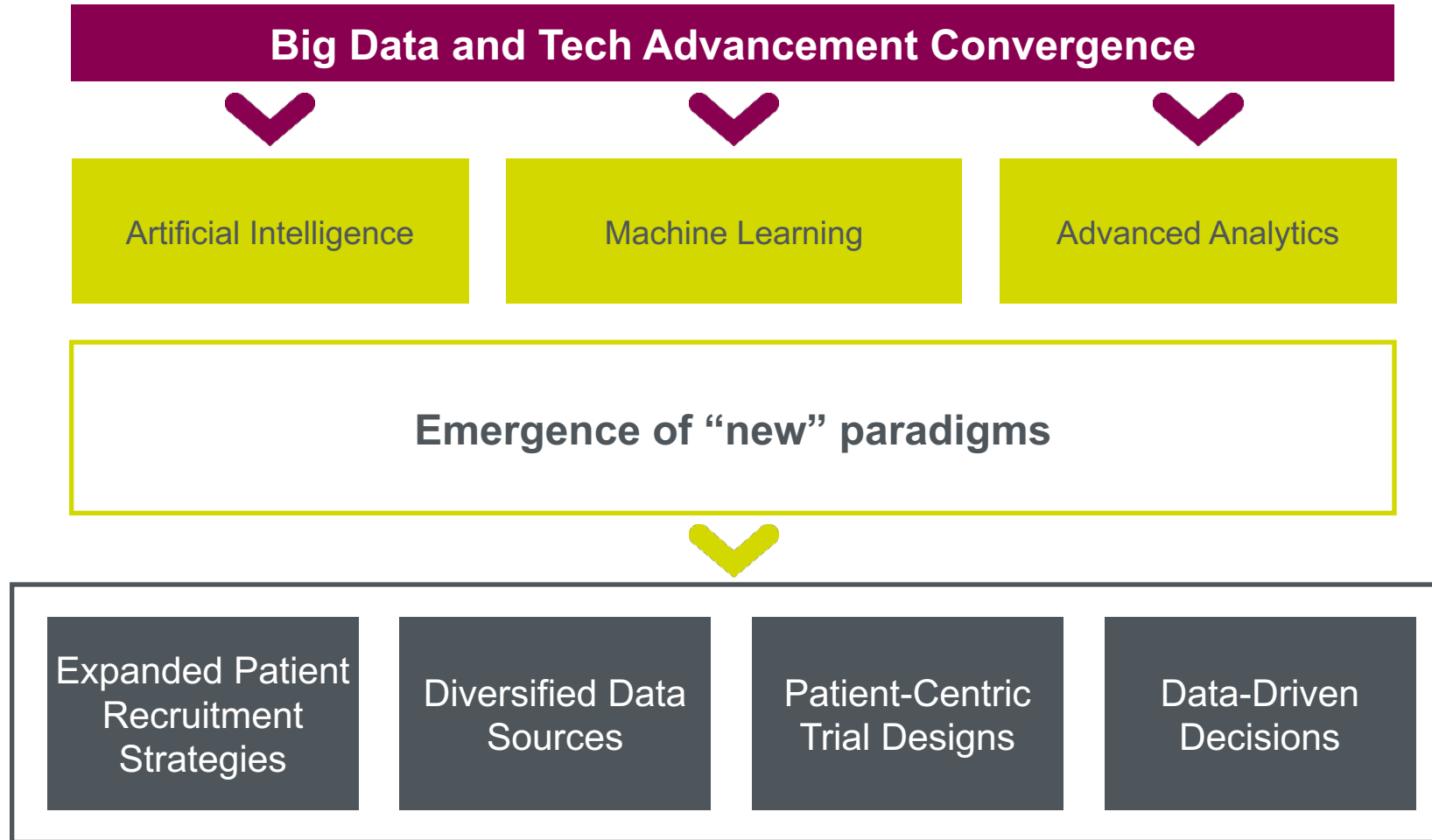
”

Bill Gates

Former CEO of Microsoft

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The New “Normal” in Clinical Development





“

Without big data analytics,
companies are blind and deaf,
wandering out onto the web like
deer on a freeway.

”

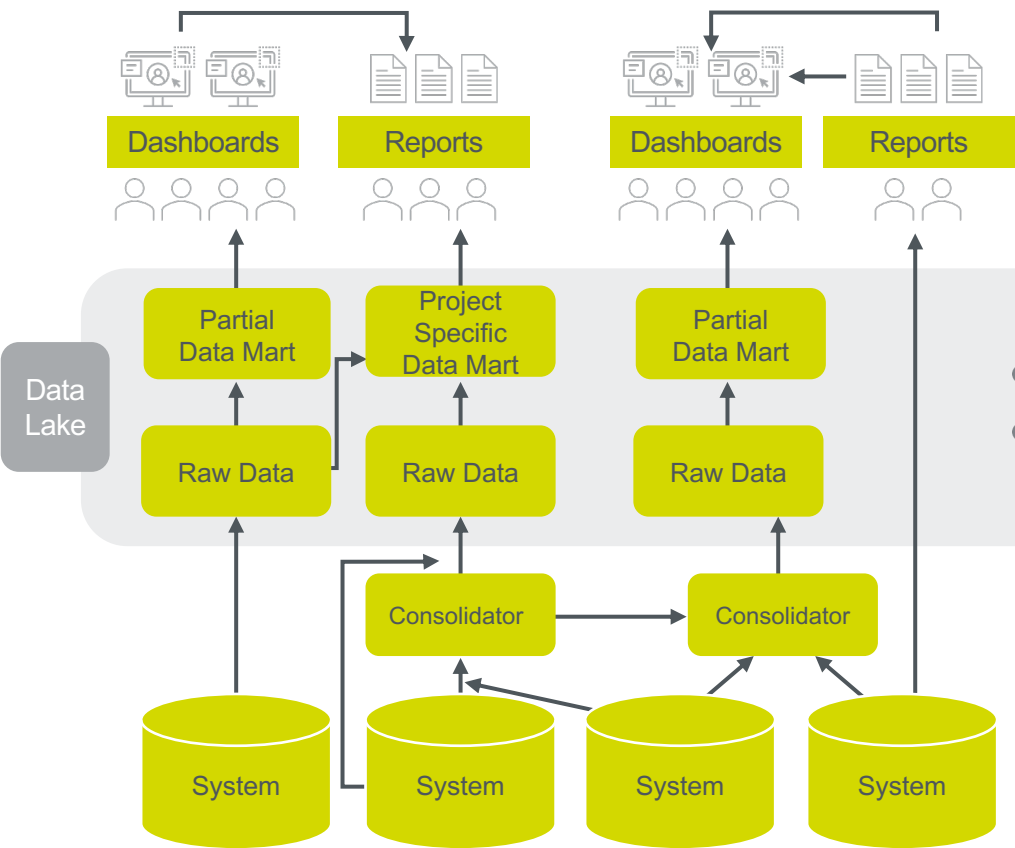
Geoffrey Moore

Management Consultant and
Author

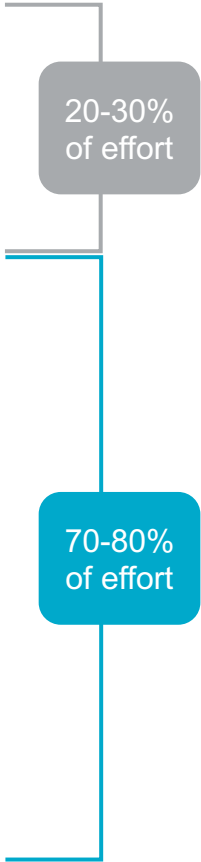
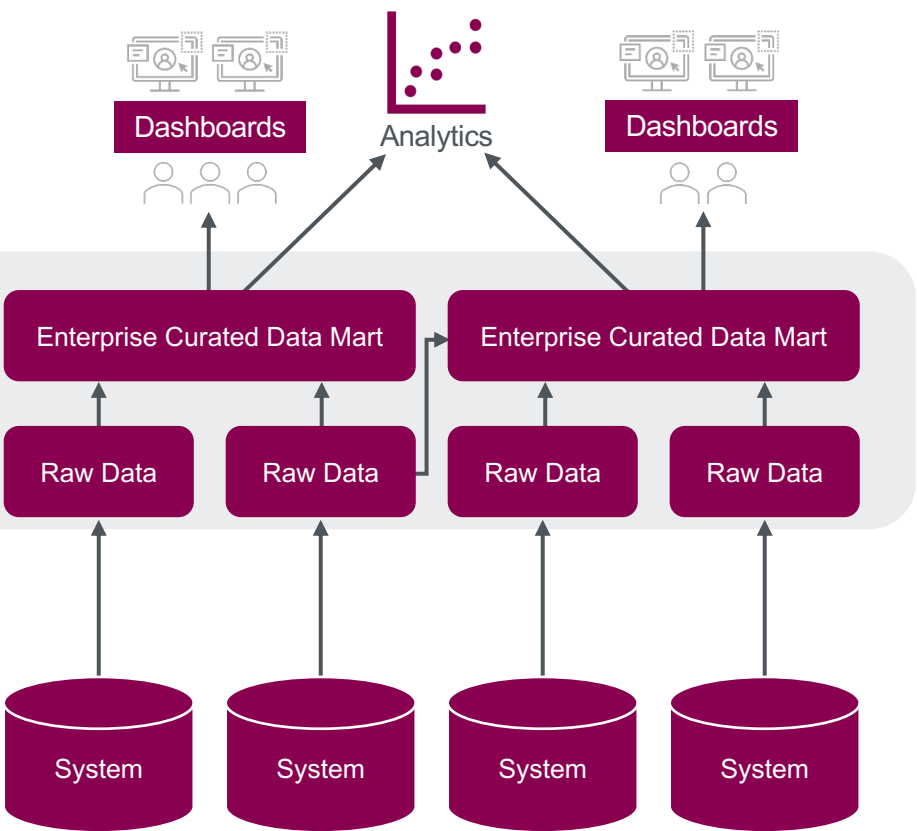
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Our Journey to a Single Source of Truth

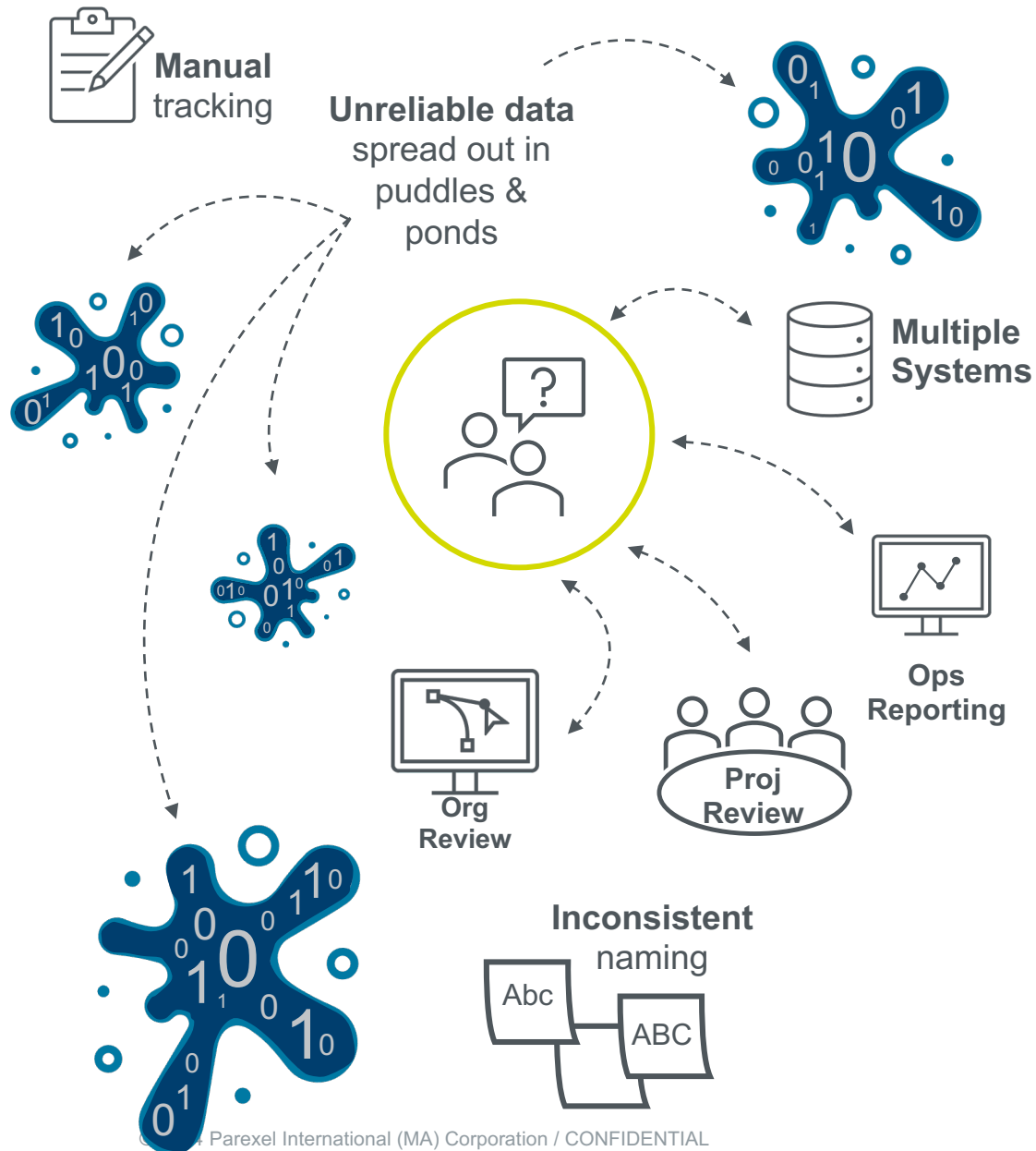
Current State



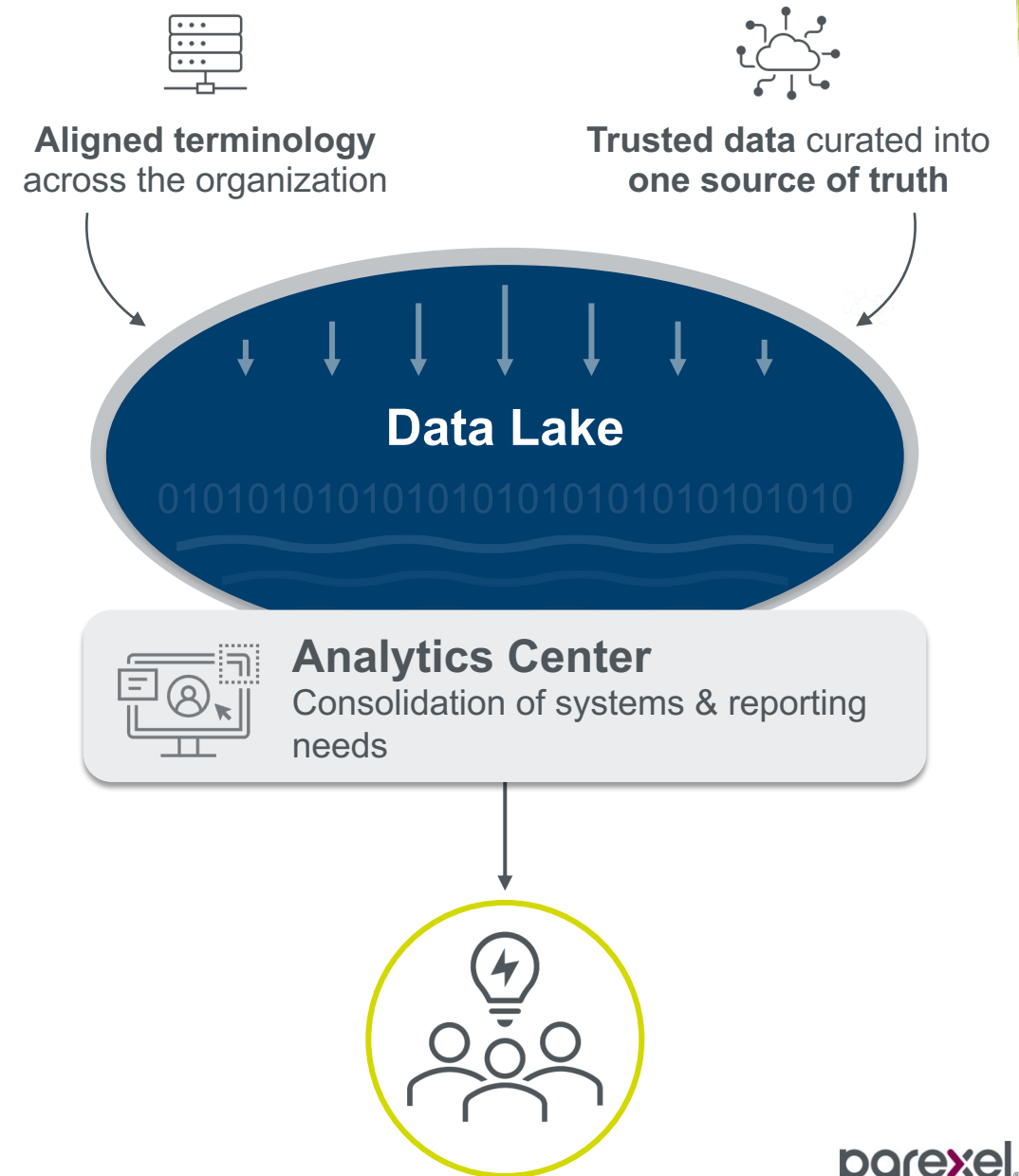
Future State



Current State

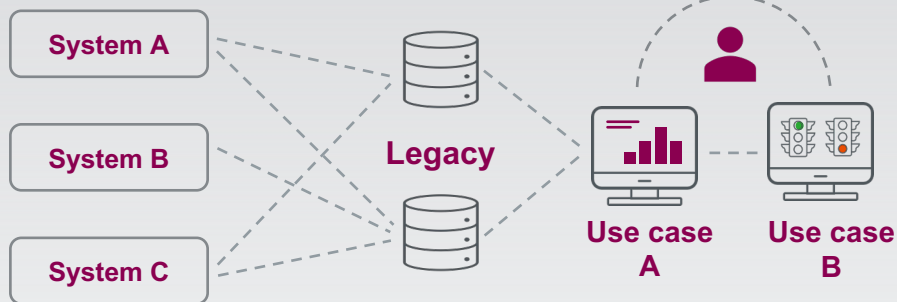


Future State

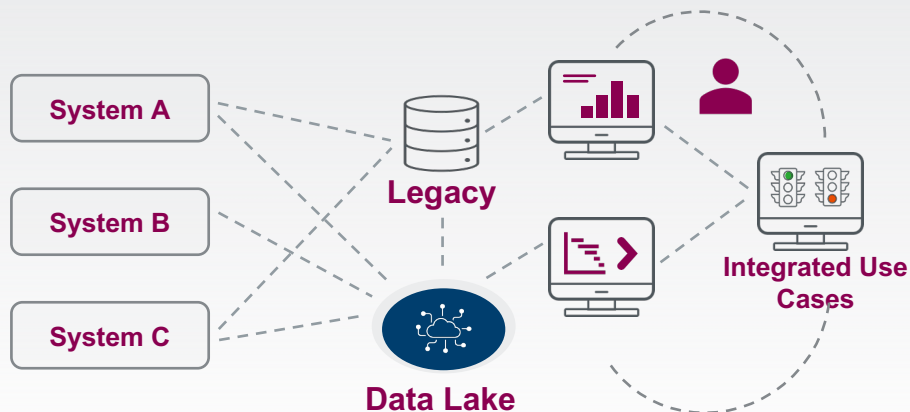


>>> Overview: Integrated Project Oversight

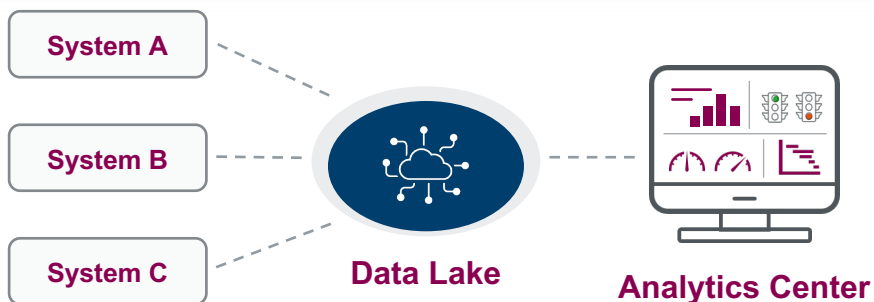
Current



Interim



Future



Integrated Project Oversight

Aligned discussion
Focused Review

Alignment On:



Risks



Status



Actions



Mitigations

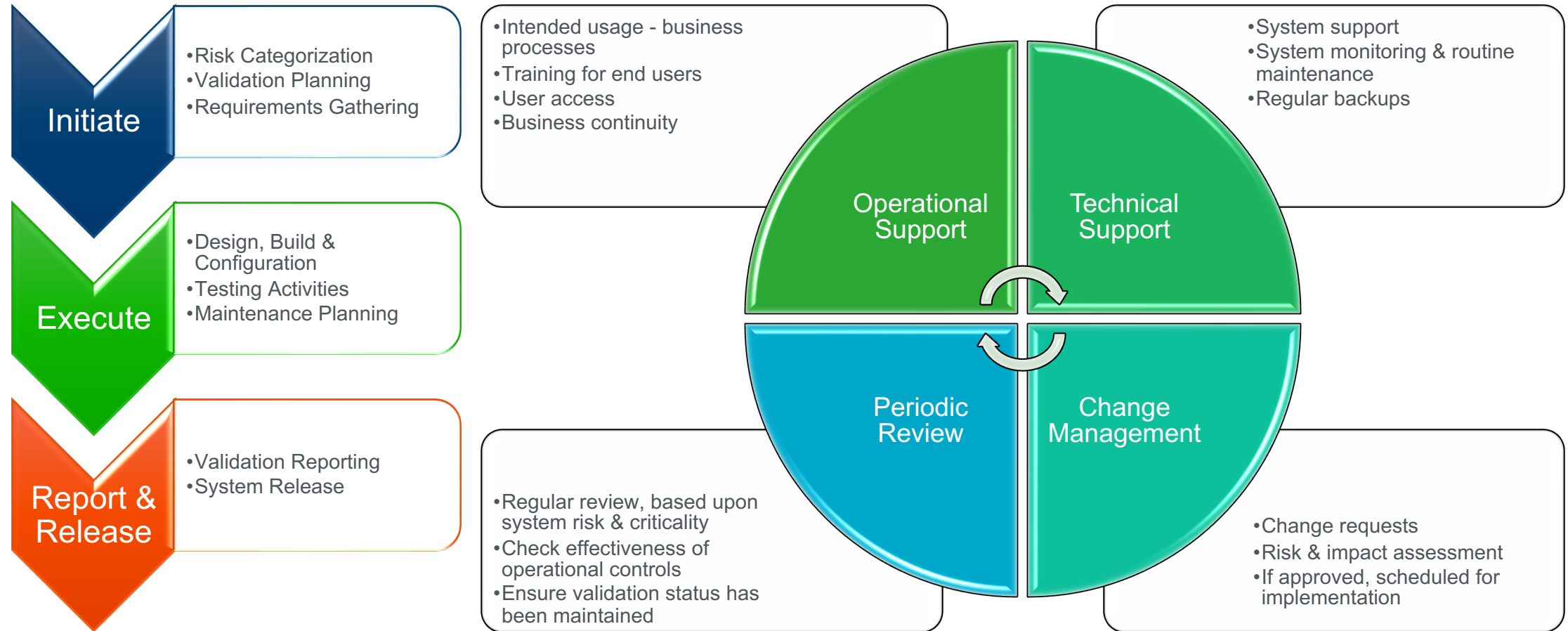


Priorities



Decisions

System Validation – Not Just a Project



Validation Project

Maintain the Validated State

“ The goal is to turn data into information, and information into insight. ”

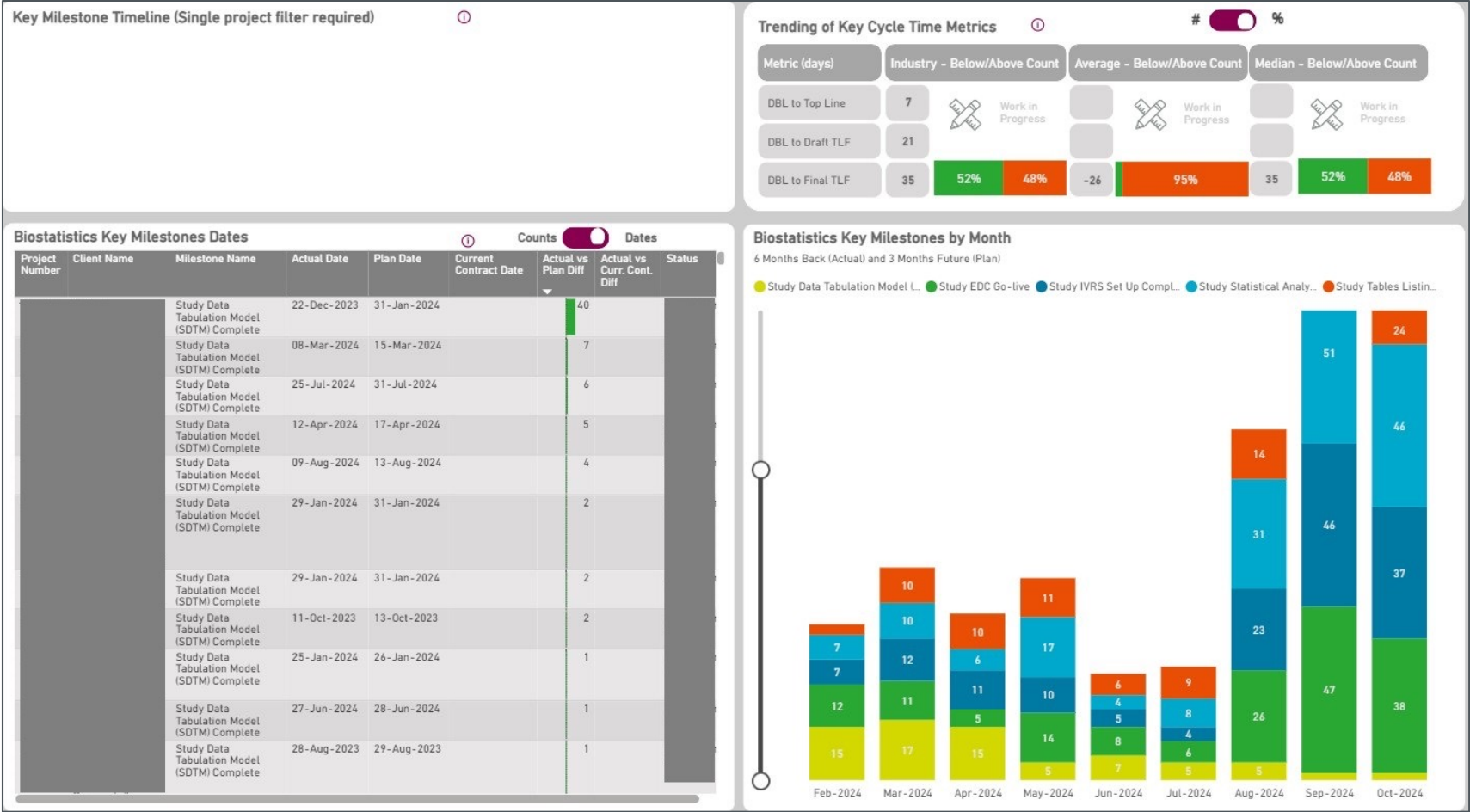
Carly Fiorina

Former CEO of Hewlett-Packard

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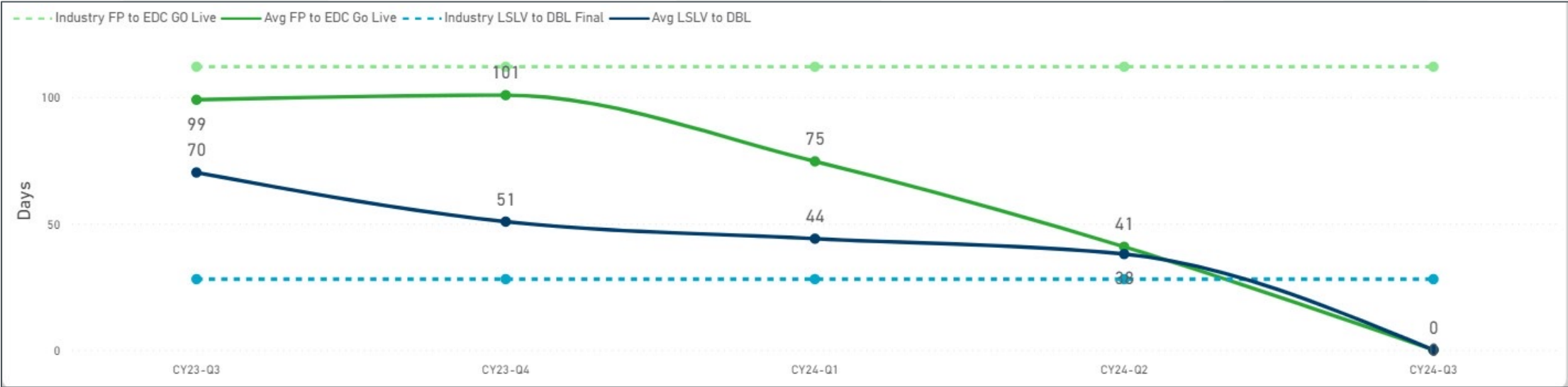
Implementation of Context-Specific Dashboards (1)

Functional-Area Milestone Analysis



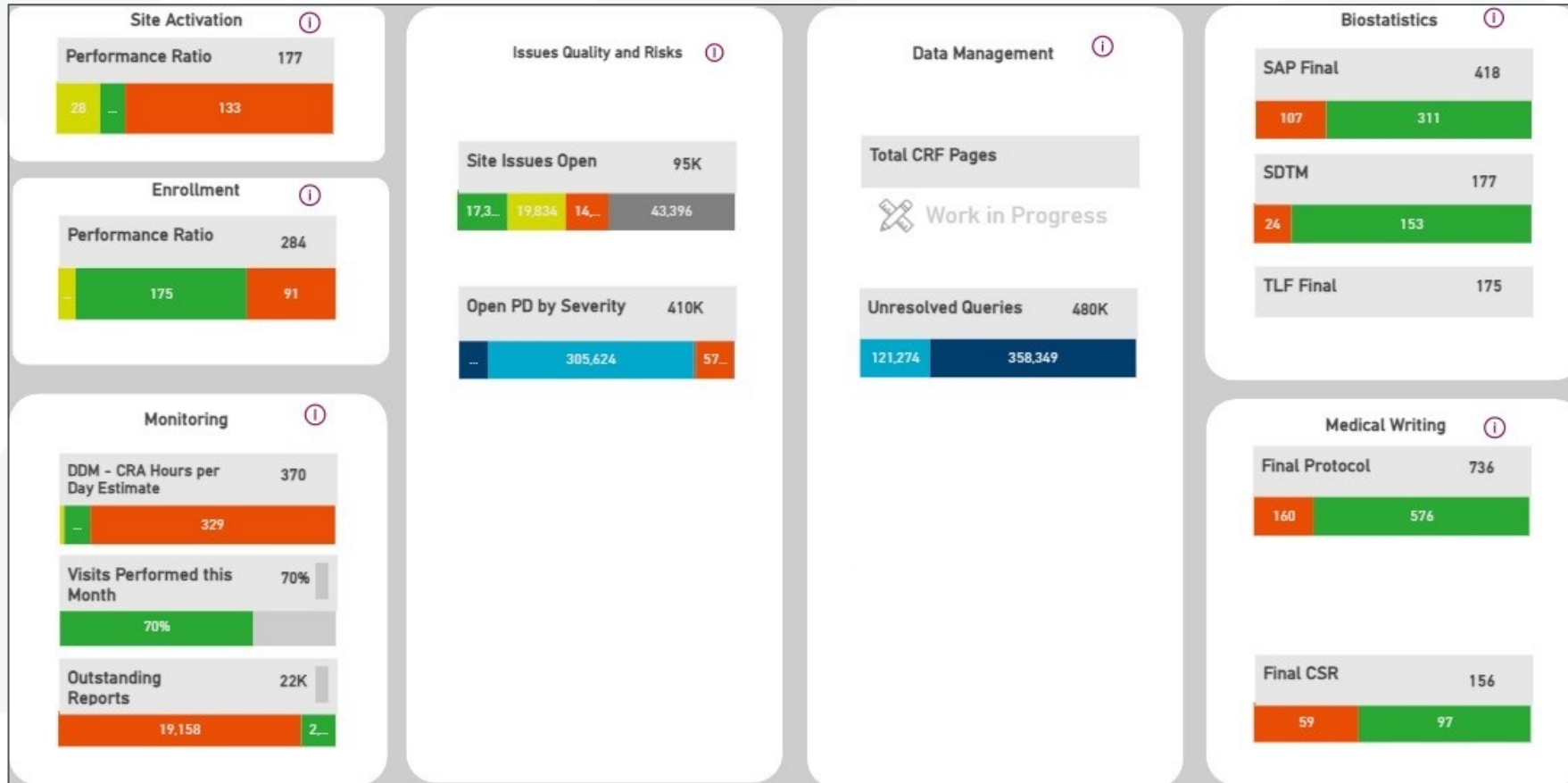
Implementation of Context-Specific Dashboards (2)

Industry vs Functional Trends Over Time



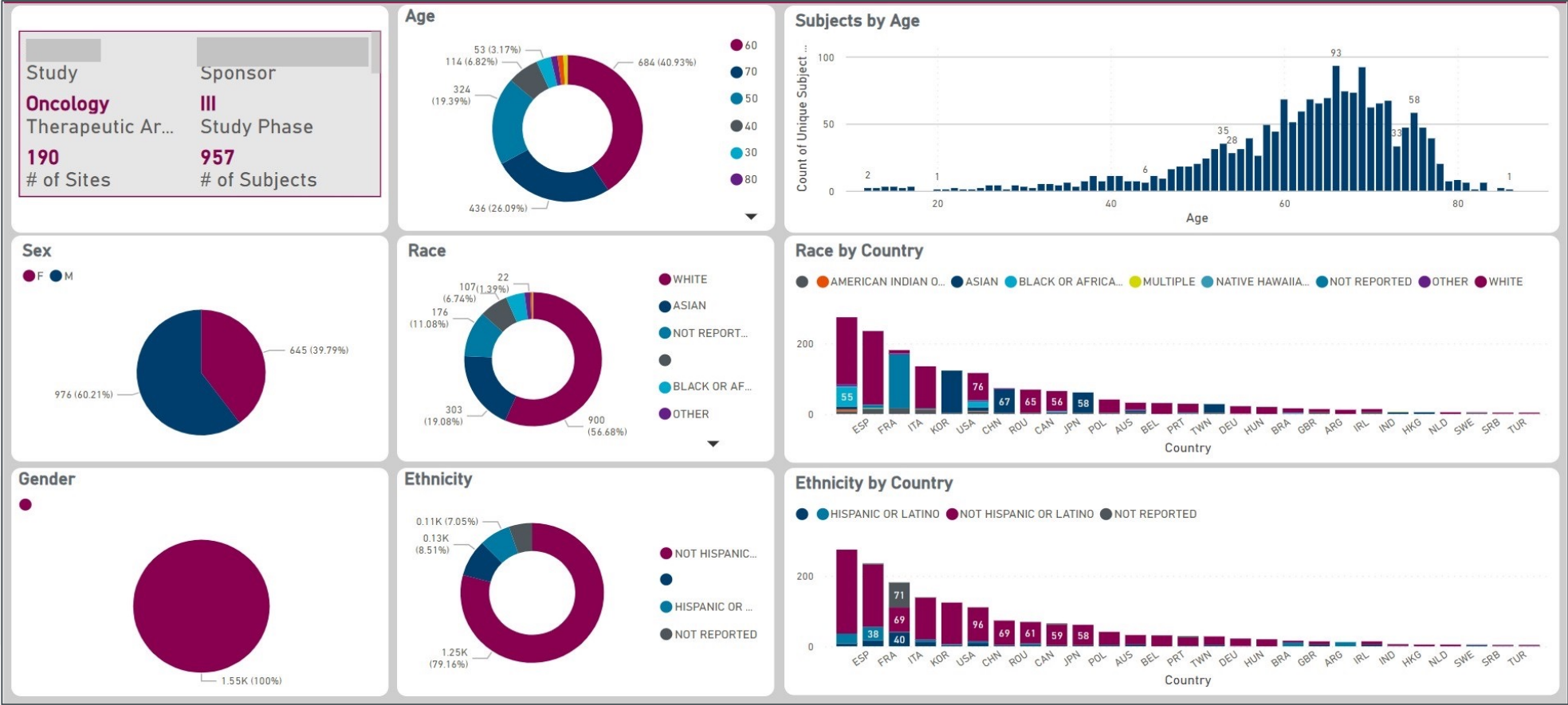
Implementation of Context-Specific Dashboards (3)

Cross-Functional Delivery Oversight



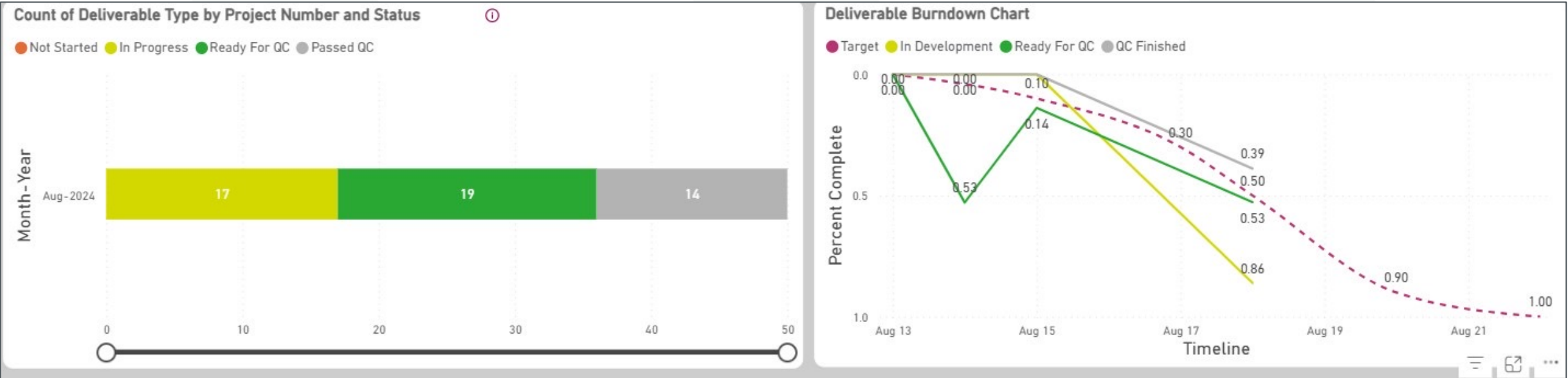
Implementation of Context-Specific Dashboards (4)

Participant Demographic Aggregation Reporting



Implementation of Context-Specific Dashboards (5)

Realtime Deliverable Progression Tracking



“ The best way to predict the future is to create it. ”

Peter Drucker (1909-2005)

Consultant and Educator

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Onward to the Future



Continued emphasis on data integration and advanced analytics



Embracing AI-driven study optimizations and patient-centric design



Strategic insights through convergence of big data and technological growth

“ The value of an idea lies in the
using of it. ”

Thomas Edison (1847-1931)

Inventor and Businessman

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Thank you

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